

REMARKS

These remarks are in response to the Office Action mailed April 30, 2009. Claims 2, 5, 14, 15, and 16 have been amended. Amendments to claim 14 are supported throughout the specification. Reference to a fluid sample is supported in the pending claims (e.g., blood, urine etc). The Examiner has indicated that the subject matter of claims 7 and 18 are allowable if incorporated into the base claims (see, page 4, paragraph 8, of the Office Action). Claim 15 has been amended to better clarify the invention. No new matter is believed to have been introduced.

I. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 2-10 and 14-18 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards and the invention.

Applicants respectfully traverse this rejection with respect to the amended claims.

The Office Action alleges that claim 14 is indefinite since the preamble recites detecting Neu5Gc, however, step (a) measures Neu5Ac and thus step (a) is unnecessary. Applicants submit that Neu5Gc-containing glycans are diverse and presented on many glycoconjugates, including glycolipids as well as *N*-linked and *O*-linked chains of glycoproteins. Also, this monosaccharide cannot by itself fill the binding site (paratope) of an antibody, which can accommodate several linked monosaccharides (see, e.g., Padlan and Kabat, 1988, Sigurskjold and Bundle, 1992, Lee et al., 2006, Houlston et al., 2007). Furthermore, structural diversity results from Neu5Gc modification such as 9-*O*-acetylation, sialyl linkage difference, and complexities of underlying glycan structure (Angata and Varki, 2002). Thus, there are actually many potential Neu5Gc-containing epitopes to be recognized by human anti-Neu5Gc antibodies. In every case, the single oxygen atom difference between Neu5Gc and Neu5Ac is crucial for antibody recognition, but the epitopes recognized are extended ones, involving the underlying glycan chain. Accordingly, "subtracting" the underlying recognition, i.e., those antibodies that recognize the underlying glycan chain of both Neu5Gc and Neu5Ac containing glycans is useful in determining the presence of Neu5Gc containing antibodies in a sample.

Applicants respectfully submit that the methods described by claim 14 identifies Neu5Gc specific antibodies by subtracting background antibodies that bind to Neu5Gc containing antigens at sites that are not specific for a Neu5Gc epitope. For example, sialic acids can contain multiple antigenic epitopes that contain either Neu5Ac or Neu5Gc, by subtracting those antibodies that recognize Neu5Ac specific epitopes or antigens comprising Neu5Ac from antibodies that bind to antigens comprising Neu5Gc, antibodies that are specific for Neu5Gc can be identified.

Claim 15 has been amended to try and better clarify the claimed invention. For example, the systems are the same except for the presence of a Neu5Gc epitope or Neu5Ac epitope. For example, the system can include the same sialic acid structure except for the change in the epitope of Neu5Gc and Neu5Ac.

For, at least, the foregoing reasons Applicants believe that is rejection may be properly withdrawn.

II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 14-18, 2-6 and 8-10 stand rejected under 35 U.S.C. §112, first paragraph because while the invention is enabling for fluid biological samples, the claims allegedly failing to comply with the enablement requirement for any biological sample. Applicants respectfully traverse this rejection.

Claim 14 has been amended to include that the sample is a fluid sample. Furthermore, the Examiner is directed to Example 5 which describes measuring antibodies and Example 6 which measures antigen in food preparations.

For at least the foregoing reasons, Applicants respectfully request withdrawal of this rejection.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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